August 8, 2019

Conformis, Inc.
Paul Smolenski
Sr. RA Manager
600 Technology Park Drive, 4th Floor
Billerica, Massachusetts 01821

Re: K190562
Trade/Device Name: iTotal Identity Cruciate Retaining Knee Replacement System
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee Joint Patellofemorotibial Polymer/Metal/Polymer Semi-Constrained Cemented Prosthesis
Regulatory Class: Class II
Product Code: JWH, OOG, OIY
Dated: July 9, 2019
Received: July 10, 2019

Dear Paul Smolenski:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's

requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For CAPT Raquel Peat, PhD, MPH, USPHS
Director
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K190562

Device Name

Conformis iTotal Identity Cruciate Retaining (CR) Knee Replacement System

Indications for Use *(Describe)*

The iTotal Identity Cruciate Retaining (CR) Knee Replacement System (KRS) is intended for use as a total knee replacement in patients with knee joint pain and disability whose conditions cannot be solely addressed by the use of a prosthetic device that treats only one or two of the three knee compartments, such as a unicondylar, patellofemoral or bicompartmental prosthesis.

The Indications for Use include:

• Painful joint disease due to osteoarthritis, traumatic arthritis, rheumatoid arthritis or osteonecrosis of the knee.

• Post traumatic loss of joint function.

• Moderate varus, valgus or flexion deformity in which the ligamentous structures can be returned to adequate function and stability.

• Failed osteotomies, hemiarthroplasties, and unicondylar, patellofemoral or bicompartmental implants.

• Revision procedures provided that anatomic landmarks necessary for alignment and positioning of the implant are identifiable on patient imaging scans.

This implant is intended for cemented use only.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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CONFORMIS

510K SUMMARY (page 1 of 5)

Submitter's Name and Address:	Conformis, Inc. 600 Technology Park Drive Billerica, MA 01821
Establishment Registration Number(s):	3009844603 and 3004153240
Date Summary was Prepared:	March 4th, 2019
Contact Person:	Paul Smolenski Sr. Regulatory Affairs Manager Telephone: 781-374-5586 Fax: 781-345-0147 E-mail: paul.smolenski@conformis.com
Trade/Device Name:	Conformis itotal Identity® Cruciate Retaining (CR) Knee Replacement System (iTotal CR KRS)
Common Name:	Total Knee Replacement System
Device Class:	Class II
Regulation Number and Description:	21 CFR 888.3560 Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis.
Classification Name:	Prosthesis, Knee, Patellofemorotibial, Semi-Constrained, Cemented, Polymer/Metal/Polymer
Product Code: (Classification)	JWH
Product Code(s): (Subsequent)	OOG: Knee Arthroplasty Implantation System OIY: Prosthesis, Knee, Patellofemorotibial, Semi-Constrained, Cemented, Polymer + Additive/Metal/Polymer + Additive
Legally Marketed Predicate Device (Primary Predicate):	Conformis iTotal® Cruciate Retaining Knee Replacement System ("iTotal CR KRS"), K180906, cleared May 16, 2018).
Legally Marketed Predicate Device	Total Joint Orthopedics, Inc., Klassic® Knee System (K180159, March 9, 2018), hereafter referred to as "TJO Klassic Knee."

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Conformis iTotal Posterior Stabilized (PS) Knee Replacement System (iTotal PS KRS), K161668, cleared July 15, 2016

Device Description:

The iTotal Identity® Cruciate Retaining Knee Replacement System (hereafter referred to as the "iTotal Identity CR KRS") is a patient specific tricompartmental faceted posterior cruciate ligament (PCL) retaining knee replacement system. The iTotal Identity CR KRS is a semi-constrained, cemented knee implant which consists of femoral, tibial, and patellar components.

Using patient imaging and a combination of proprietary and off the shelf software, a patient-specific implant is designed that best meets the geometric and anatomic requirements of the specific patient. The femoral component is manufactured from cobalt chromium molybdenum (CoCrMo) alloy. The tibial component includes a metal tray and tray keel stem extension manufactured from titanium (Ti6AL4V-ELI) alloy, a tibial tray keel cap manufactured from polyethylene (UHMWPE), and either one or two polyethylene inserts. These inserts may be manufactured from either UHMWPE or iPoly® XE (a highly cross-linked Vitamin E infused polyethylene). The patellar component is provided in either a round or oval dome shape and may be manufactured from either UHMWPE or iPoly® XE.

For user convenience, and similar to the primary predicate iTotal CR KRS, single-use, patient-specific ancillary orthopedic manual surgical instruments designed for use with the proposed iTotal Identity CR KRS are provided to assist in the positioning of the total knee replacement components intraoperatively and in guiding the cutting of bone. In addition, reusable orthopedic manual surgical instruments are provided separately.

Indications for Use:

The iTotal Identity® Cruciate Retaining (CR) Knee Replacement System (KRS) is intended for use as a total knee replacement in patients with knee joint pain and disability whose conditions cannot be solely addressed by the use of a prosthetic device that treats only one or two of the three knee compartments, such as a unicondylar, patellofemoral or bicompartmental prosthesis.

The Indications for Use include:

- Painful joint disease due to osteoarthritis, traumatic arthritis, rheumatoid arthritis or osteonecrosis of the knee.
- Post traumatic loss of joint function.

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- Moderate varus, valgus or flexion deformity in which the ligamentous structures can be returned to adequate function and stability.
- Failed osteotomies, hemiarthroplasties, and unicondylar, patellofemoral or bicompartmental implants.
- Revision procedures provided that anatomic landmarks necessary for alignment and positioning of the implant are identifiable on patient imaging scans.

This implant is intended for cemented use only.

Summary of Technological Characteristics:

The rationale for substantial equivalence is based on consideration of the following device use and characteristics

Intended Use:
The proposed iTotal Identity CR KRS and predicate devices are intended to be used as total knee replacements. The implantable components are intended for single-use only in a single patient.

Indications for Use:
The proposed iTotal Identity CR KRS and the primary predicate iTotal CR KRS have identical indications for use.

Operating Principal/Fundamental Technology:
The proposed and predicate devices are semi-constrained, cemented knee implants that consist of three primary components; femoral, tibial, and patellar.

Single-use, patient-specific ancillary surgical instruments are provided for use with both the primary predicate iTotal CR KRS and proposed iTotal Identity CR KRS to assist with surgical implantation.

Reusable ancillary surgical instruments, provided in a reusable instrument tray, are used with the predicate and proposed devices. These instruments assist with surgical implantation.

Design:
The proposed and predicate devices have the same basic design characteristics as they are comprised of three primary components: femoral, tibial, and patellar. The proposed iTotal Identity CR KRS offers a tibial tray stem extension and tibial tray keel cap, which are features that are also offered with the predicate TJO Klassic Knee.

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Materials:
The same biocompatible materials (CoCrMo, UHMWPE, and iPoly®XE) are used to manufacture the femoral, tibial insert, and patellar components of both the proposed iTotal Identity CR KRS and primary predicate iTotal CR KRS.

Titanium alloy (Ti6AL4V-ELI), is used to manufacture the tibial tray and tibial stem extension of the proposed iTotal Identity CR KRS. The tibial tray and stem extension of the predicate TJO Klassic Knee are also manufactured from titanium alloy (Ti6AL4V).

The tibial tray keel cap of the proposed iTotal Identity CR KRS is made from the same biocompatible material (UHMWPE) that is currently used to manufacture tibial inserts and patellar implants of the primary predicate device.

The same biocompatible materials (nylon, stainless steel and R-Radel) are used to manufacture the single-use and reusable surgical instrumentation of both the primary predicate and proposed iTotal Identity CR KRS.

Sterilization:
The implant components of both the proposed iTotal Identity CR KRS and predicate devices are provided sterile in double pouches (SAL 1.0 x 10^{-6}).

The single-use surgical instruments used with the proposed and primary predicate device are provided sterile in double pouches (SAL 1.0 x 10^{-6}).

The reusable surgical instruments used with the proposed and predicate devices are provided non-sterile.

Substantial Equivalence

The iTotal Identity CR KRS, subject of this premarket notification, is substantially equivalent to the following predicate devices:

Conformis iTotal CR KRS
(K180906. cleared May 16, 2018).

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Conformis iTotal PS KRS
(K161668, cleared July 15, 2016)

TJO Klassic Knee System
(K180159, cleared March 9, 2018)

Substantial equivalence is based on intended use and the technological characteristics of the proposed iTotal Identity CR KRS, as well as non-clinical testing conducted to confirm that proposed iTotal Identity CR KRS is substantially equivalent to the predicate devices. Specifically, the following testing was performed:

- Cadaver (instrumentation testing & usability)
- Insert interlock/Modularity
- Tibial tray stem fatigue
- Tibial tray stem assembly/disassembly torque
- Tibial tray and stem extension particle analysis/fretting corrosion
- Biocompatibility
- MRI Compatibility
- Patella test justification
- Tibial Insert justification (contact area, range of motion, constraint testing).
- Sterilization validation
- Reusable instrument cleaning & sterilization (new tray and new instruments)

All testing has demonstrated that the proposed iTotal Identity CR KRS is substantially equivalent to the predicate devices.

Conclusion

Based on intended use, technological characteristics, and testing conducted, it is concluded that the proposed iTotal Identity CR KRS is substantially equivalent to the predicate devices.